REMARKS/ARGUMENTS

Claims 36-81 are pending in the instant application. Claims 50-77 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants in this amendment. Claims 36, 41, 42, 78 and 81 have been amended. No new matter has been added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed July 26, 2002.

Applicants still respectfully disagree with this Restricition given the sequence similarities and activities of the proteins. Applicants believe this close relationship is better suited to a species election rathan thana restricition. However, in an earnest effort to facilitate the prosecution of this case, Applicants have canceled nonelected claims 50-77. Further, Applicants have amended claims 36, 42 and 78 partially drawn to non-elected inventions to be drawn only to the elected invention.

In light of the finality of this Restriction Requirement,

Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Objection to Priority Claim of Specification

The specification has been objected to because the status of the earlier application is incorrect. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the priority claim to provide the correct status for the earlier filed application.

Withdrawal of this objection is therefore respectfully requested.

III. Objection to Drawings

Applicants are submitting herewith drawings corrected in accordance with the Notice of Drafsperson's Patent Drawing Review. No new matter is added by the corrections to the drawings and their entry is respectfully requested.

IV. Claim Objections

Claims 36, 42 and 78 have been objected to as being partially drawn to non-elected inventions. As discuss in Section I, supra, these claims have been amended to delete non-elected inventions. Accordingly withdrawal of this objection is respectfully requested.

V. Rejection of Claims 36-49 and 78-81 under 35 U.S.C. § 112, second paragraph

Claims 36-49 and 78-81 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner suggests that claims 36, 41, 78 and 81, and the claims which depend therefrom, are indefinite in the recitation of "greater than about" or "at least about" because it renders the claims vague and confusing.

Thus, in accordance with the Examiner's suggestion, Applicants have deleted the term "about" from these phrases of claims 36, 41, 78 and 81.

Withdrawal of this rejection under 35 U.S.C. § 112, second paragraph is therefore respectfully requested.

VI. Rejection of Claims 36-41, 43-49, and 78-81 under 35 U.S.C. § 112, first paragraph

Claims 36-41, 43-49 and 78-81 have been rejected under 35 U.S.C. § 112, first paragraph. The Examiner has acknowledged the specification to be enabling for the polypeptide of SEQ ID NO:11. However, the Examiner suggests that the specification does not

reasonably provide enablement for any antifreeze protein which has at least 70% sequence identity to the polypeptide of SEQ ID NO:11. Specifically, the Examiner suggests that due to the lack of relevant examples, the amount of information provided, the lack of knowledge of the critical structural elements required to display the desired characteristics and the function, and the unpredictability of the prior art in regard to function based on homology, one of skill in that art would have to go through the burden of undue experimentation in order to screen and isolate those polypeptides, as encompassed by the claims, with antifreeze function.

Applicants respectfully traverse this rejection.

In accordance with MPEP § 2164.08, all questions of enablement are evaluated against the claimed subject matter. Further, the enablement of the subject matter of each claim must be considered as a whole, not when parts are analyzed individually. See MPEP § 2164.08.

Claims of the instant application are drawn to an isolated or recombinantly expressed antifreeze protein having a calculated molecular weight of between 7 and 13 kDa; a thermal hysteresis activity of greater than 1.5°C at a concentration of about 1 mg/mL; an N-terminal amino acid motif as set forth in SEQ ID

NO:3; specific binding to an antibody raised against an antifreeze protein YL-1 (SEQ ID NO:11); **and** at least 70% amino acid sequence identity to an antifreeze protein of YL-1 (SEQ ID NO:11). Accordingly, the Examiner's focus of this rejection upon the state of the art relating to predictability of sequence comparison alone to determine a protein's function is improper since this is only one part of the claimed invention. Additional parts of the claimed polypeptide include molecular weight determination, the methods for which are clearly set forth in the specification at page 39, line 19 through page 40, line 18; a defined thermal hysteresis activity at a defined concentration, methods for determination or which are clearly set forth in the specification at page 40, line 24, through page 42, line 12; an N-terminal amino acid motif as set forth in SEQ ID NO:3 and taught in the Sequence Listing filed with the application; and specific binding to an antibody raised against an antifreeze protein of YL-1 (SEQ ID NO:11), methods for determination of which are set forth in the specification at page 29, line 15 through page 35, line 19.

Further, methods for determining the amino acid sequence of a polypeptide and its % identity are set forth in the

specification at page 39, lines 5-17 and page 10, line 25, through page 11, line 6, respectively. As taught at page 10, line 27 of the specification, software such as GAP and BESTFIT, which are publicly available, can be used to determine identity between two sequences. Polypeptides with 70% identity with SEQ ID NO:11 can be identified routinely using such software. One of skill in the art can then routinely conduct the methods taught in the specification to make and use polypeptides in addition to the 5 acknowledged by the Examiner to be exemplified in the specification which meet all the other requirements of the claims in a manner reasonably correlated with the scope of the claims. Such experimentation is not considered undue since the specification provides detailed guidance with respect to the direction in which these experiments should proceed. See MPEP § 2164.06.

Further, as acknowledged by the Examiner in the Office Action at page 6, the specification discloses the structure of 5 antifreeze proteins. Thus, contrary to the Examiner's suggestion at page 7 of the Office Action, relevant working examples are not lacking in the instant specification.

One reasonably skilled in the art can clearly make and use polypeptides with a molecular weight of between 7 and 13 kDa, a

thermal hysteresis activity of greater than 1.5°C at a concentration of about 1 mg/mL, an N-terminal amino acid motif of SEQ ID NO:3, specific binding to an antibody raised against an antifreeze protein YL-1 (SEQ ID NO:11), **and** at least 70% amino acid sequence identity to an antifreeze protein of YL-1 as claimed from the disclosure in the patent application coupled with information known in the art without undue experimentation. Thus, the specification meets the test of enablement as set forth in MPEP § 2164.01.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph is therefore respectfully requested.

VII. Clean Copy of all pending claims

In accordance with the Examiners request at paragraph 12 of this Office Action, Applicants are submitting a clean copy of the pending claims including amendments made herein.

VIII. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

Kathleen A. Tyrrell
Registration No. 38,350

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LICATA & TYRRELL P.C.
66 E. Main Street
Marlton, New Jersey 08053
(856) 810-1515

Clean Version of Pending Claims:

Claims 1-35 (canceled)

Claim 36 (currently amended): An isolated or recombinantly expressed antifreeze protein, said protein comprising the following:

(i) a calculated molecular weight of between 7 and 13 kDa;

(ii) a thermal hysteresis activity of greater than 1.5°C at a concentration of about 1 mg/mL;

(iii) the N-terminal amino acid motif set forth in SEQ ID NO:3;

(iv) specific binding to an antibody raised against an antifreeze protein of YL-1 (SEQ ID NO:11); and

(v) at least 70% amino acid sequence identity to an antifreeze protein of YL-1 (SEQ ID NO:11).

Claim 37 (original): The isolated or recombinant antifreeze protein of claim 36, wherein the antifreeze protein comprises at least one repeat of the 12 contiguous amino acid motif set forth in SEQ ID NO:1.

Claim 38 (original): The isolated or recombinant antifreeze protein of claim 37, wherein the number of repeats of the motif is from 5 to 12.

Claim 39 (original): The isolated or recombinant antifreeze protein of claim 36, wherein the calculated molecular weight of the antifreeze protein is between 8 and 12 kDa.

Claim 40 (original): The isolated or recombinant antifreeze protein of claim 36, wherein the antifreeze protein includes the subsequence of amino acids set forth in SEQ ID NO:4.

Claim 41 (currently amended): The isolated or recombinant antifreeze protein of claim 36, wherein the thermal hysteresis activity is greater than 2°C at a concentration of about 1 mg/mL.

Claim 42 (currently amended): The isolated or recombinant antifreeze protein of claim 36, wherein the antifreeze protein is YL-1 (SEQ ID NO:11).

Claim 43 (original): The isolated or recombinant antifreeze protein of claim 36, wherein the antifreeze protein is expressed by a baculovirus vector.

Claim 44 (original): The isolated or recombinant antifreeze protein of claim 36, wherein the antifreeze protein is synthesized by a bacterial cell, a fungus cell, a plant cell, or an animal cell.

Claim 45 (original): The isolated or recombinant antifreeze protein of claim 36, wherein the antifreeze protein is synthesized by a yeast cell.

Claim 46 (original): The isolated or recombinant antifreeze protein of claim 36, wherein the antifreeze protein is synthesized by an animal cell.

Claim 47 (original): The isolated or recombinant antifreeze protein of claim 36, wherein the nucleic acid encoding the antifreeze protein is synthesized by an insect cell.

Claim 48 (original): The isolated or recombinant antifreeze protein of claim 36, wherein the antifreeze protein is derived from *Tenebrio* sp.

Claim 49 (original): The isolated or recombinant antifreeze protein of claim 44, wherein the antifreeze protein is expressed externally from the cell.

Claims 50-77 (canceled)

Claim 78 (currently amended): A liquid comprising a recombinant antifreeze protein, said antifreeze protein comprising the following:

(i) a calculated molecular weight of between 7 and 13 kDa;

(ii) a thermal hysteresis activity of greater than 1.5°C at a concentration of about 1 mg/mL;

(iii) the N-terminal amino acid motif set forth in SEQ ID NO:3;

(iv) specific binding to an antibody raised against an antifreeze protein of YL-1 (SEQ ID NO:11); and

(v) at least 70% amino acid sequence identity to an antifreeze protein of YL-1 (SEQ ID NO:11).

Claim 79 (original): The liquid of claim 78, wherein the antifreeze protein comprises at least one repeat of the 12 contiguous amino acid motif set forth in SEQ ID NO:1.

Claim 80 (original): The liquid of claim 78, wherein the concentration of antifreeze protein is between about one part per billion (1 µg/L) to about one part per thousand (1 g/L).

Claim 81 (currently amended): The liquid of claim 78, wherein the thermal hysteresis activity is greater than 2°C at a concentration of about 1 mg/mL.